UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

JUDITH REIMANN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CASE NO. 1:08-cv-0830-DFH-DML
	)	
	)	
ANTHEM INSURANCE COMPANIES, INC.,	)	
	)	
Defendant.	)	

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Introduction

Plaintiff Judith Reimann suffers from cancer that has metastasized and affects both lobes of her liver, her pancreas, and her small intestine. After finding that other modes of treatment were not successful, her physicians at Indiana University Hospital proposed an unusually aggressive form of treatment: surgery to remove the affected tissue in all organs, including what is known as a multivisceral transplant, which would transplant a liver, pancreas, and small intestine from a deceased donor. The transplant surgery is estimated to cost about one million dollars.

Defendant Anthem Insurance Companies, Inc. underwrites and administers a health insurance plan that covers Mrs. Reimann through her employer. Anthem has denied coverage of the proposed multivisceral transplant. Anthem has found that the procedure is not medically necessary because there is not sufficient evidence to expect that it would benefit a patient like Mrs. Reimann whose cancer has metastasized beyond the liver. That decision has been based on the views of four outside, independent specialists who have no financial stake in the outcome of this case.

Plaintiff Reimann moved for a preliminary injunction ordering Anthem to cover the costs of the proposed transplant surgery. Pursuant to the parties' stipulation, the court has consolidated the hearing on the preliminary injunction with the final decision on the merits, as allowed by Rule 65(a)(2) of the Federal Rules of Civil Procedure. The case is governed by the federal Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1001 *et seq*. Because the health insurance policy provides that Anthem has discretion to interpret and apply the policy, Anthem's denial is subject to deferential review for abuse of discretion. See generally *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. —, 128 S. Ct. 2343 (2008). The court is fully aware of the life-and-death stakes in this case. The case was reassigned to this judge on Friday, October 17, 2008, and the court heard argument on Tuesday, October 21, 2008. As explained in detail below, the court concludes that Anthem's denial of coverage was not an abuse of discretion or otherwise unreasonable. Anthem made some procedural mistakes in its handling

of the case, but those mistakes were either harmless or have already been remedied by Anthem. The mistakes did not deny Mrs. Reimann a full and fair review of her case. On the merits, Mrs. Reimann's excellent doctors have explained why they believe the multivisceral transplant might help her, but they have not identified scientific evidence showing that it is likely to help a patient as ill as she is. The four independent experts who reviewed the case understood the issue and explained that the surgery is not proven for patients with metastatic cancer, especially extending outside the liver. Plaintiff has failed to show that Anthem abused its discretion by relying on their findings. Accordingly, the court will enter judgment denying relief to plaintiff.

Findings of Fact

I. *Plaintiff, Her Illness, and Her Doctors' Recommendation*

Plaintiff Judith Reimann is employed by the Hillcrest Country Club in Indianapolis, through which she receives health insurance with defendant Anthem. In December 2006, Mrs. Reimann saw a cardiologist for problems with high blood pressure. During an ultrasound test for the blood pressure issues, lesions were discovered on her liver. In February 2007, Mrs. Reimann was diagnosed with carcinoid tumor of the liver. She received treatment, including chemotherapy, at the Central Indiana Cancer Center. The chemotherapy was not successful. In January 2008, Mrs. Reimann sought treatment from the Indiana University School of Medicine. In February 2008, her doctors discovered that she

also had abnormal nodes in her peri-pancreatic region and a carcinoid tumor on her duodenum (small intestine).

These are neuroendocrine tumors (also known as pancreatic endocrine tumors), which are a relatively rare form of cancer. They are less biologically aggressive than some other forms of cancer, and they can be treated by surgical removal of the tumors. The relatively slow growth provides what Mrs. Reimann's doctors have described as "a window for definitive treatment." Without treatment, though, the tumors will eventually progress. They will ultimately be fatal to Mrs. Reimann if they are not treated adequately. AR 0176.[1]

Dr. Rodrigo Vianna is the director of the intestinal transplant program at the Indiana University School of Medicine. Dr. Vianna has recommended surgical resection of the tumors in the liver, small intestine, and peripancreatic region. He has concluded that surgical removal of the cancerous tissue is the only form of treatment that offers any hope of curing Mrs. Reimann. Because so much tissue will probably need to be removed, Dr. Vianna recommends that the surgery be done with the ability to perform a multivisceral transplant of the liver, pancreas, and small intestine from a deceased donor. Dr. Vianna and his colleagues have concluded "that primary resection with multivisceral transplant backup is the

[1]Citations to "AR —" are to pages of the administrative record, and citations to "SAR —" are to pages of the supplemental administrative record, all filed by Anthem.

optimal treatment for her tumor, providing her the greatest chance of cure and long-term survival." AR 0176.

Indiana University is one of approximately 29 cancer centers in the United States that perform multivisceral transplants. SAR 0015. Dr. Vianna reports that Indiana University has performed 46 intestinal and multivisceral transplants in adults since 2003 with an 89% overall adult multivisceral survival rate, which makes Indiana University's one of the most successful programs in the world. AR 0171, 0176. The transplant selection committee for Indiana University Hospital has approved Mrs. Reimann for this transplant procedure. Dr. Vianna estimates that the proposed surgery and follow-up care would cost approximately one million dollars.

II. *Anthem Policy Terms*

Mrs. Reimann's right to health insurance coverage is governed by the Anthem health insurance policy purchased by her employer. The policy includes coverage for organ transplant surgery, but only if it is medically necessary. AR 0049. The policy defines "medically necessary" as follows:

> Medically Necessary/Medical Necessity – An intervention that is or will be provided for the diagnosis, evaluation and treatment of a condition, illness, disease or injury and that is determined by Us to be:
>
> - Medically appropriate for and consistent with the symptoms and proper diagnosis or treatment of the Member's condition, illness, disease or injury;

- Obtained from a Provider;
- Provided in accordance with applicable medical and/or professional standards;
- Known to be effective, as proven by scientific evidence, in materially improving health outcomes;
- The most appropriate supply, setting or level of service that can safely be provided to the Member and which cannot be omitted consistent with recognized professional standards of care (which, in the case of hospitalization, also means that safe and adequate care could not be obtained in a less comprehensive setting);
- Cost-effective compared to alternative interventions, including no intervention ("cost effective" does not mean lowest cost);
- Not Experimental/Investigative;
- Not primarily for the convenience of the Member, the Member's family or the Provider.
- Not otherwise subject to an exclusion under this Certificate.

The fact that a Provider may prescribe, order, recommend, or approve care, treatment, services or supplies does not, of itself, make such care, treatment, services or supplies Medically Necessary.

AR 0096-97.

The Anthem health insurance policy defines "Experimental/ Investigative" as follows:

> Any Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service or supply used in or directly related to the diagnosis, evaluation, or treatment of a disease, injury, illness, or other health condition which We determine to be unproven. For how this is determined, see the "Non-Covered Services/Exclusions" section.

AR 00095. Turning to the cited section, one finds a detailed explanation of the exclusion, including the following explanation:

> Any Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply used in or directly related to the diagnosis, evaluation, or treatment of a disease, injury, illness, or other health condition which We determine in Our sole discretion to be Experimental/Investigative is not covered under the Plan.
>
> We will deem any Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply to be Experimental/Investigative if We determine that one or more of the following criteria apply when the service is rendered with respect to the use for which benefits are sought. The Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply:
>
> - cannot be legally marketed in the United States without the final approval of the Food and Drug Administration (FDA), or other licensing or regulatory agency, and such final approval has not been granted;
> - has been determined by the FDA to be contraindicated for the specific use; or
> - is provided as part of a clinical research protocol or clinical trial or is provided in any other manner that is intended to evaluate the safety, toxicity, or efficacy of the Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply; or
> - is subject to review and approval of an Institutional Review Board (IRB) or other body serving a similar function; or
> - is provided pursuant to informed consent documents that describe the Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply as Experimental/Investigative, or otherwise indicate that the safety, toxicity, or efficacy of the Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply is under evaluation.
>
> Any service not deemed Experimental/Investigative based on the criteria above may still be deemed Experimental/Investigative by Us. In

determining whether a Service is Experimental/Investigative, We will consider the information described below and assess whether:

- the scientific evidence is conclusory concerning the effect of the service on health outcomes;

- the evidence demonstrates the service improves net health outcomes of the total population for whom the service might be proposed by producing beneficial effects that outweigh any harmful effects;

- the evidence demonstrates the service has been shown to be as beneficial for the total population for whom the service might be proposed as any established alternatives; and

- the evidence demonstrates the service has been shown to improve the net health outcomes of the total population for whom the service might be proposed under the usual conditions of medical practice outside clinical investigatory settings.

The information considered or evaluated by Us to determine whether a Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply is Experimental/Investigative under the above criteria may include one or more items from the following list which is not all inclusive:

- published authoritative, peer-reviewed medical or scientific literature, or the absence thereof; or

- evaluations of national medical associations, consensus panels, and other technology evaluation bodies; or

- documents issued by and/or filed with the FDA or other federal, state or local agency with the authority to approve, regulate, or investigate the use of the Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply; or

- documents of an IRB or other similar body performing substantially the same function; or

- consent document(s) and/or the written protocol(s) used by the treating Physicians, other medical professionals, or facilities or by other treating Physicians, other medical professionals or facilities studying substantially the same Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply; or

- medical records; or
- the opinions of consulting Providers and other experts in the field.

We have the sole authority and discretion to identify and weigh all information and determine all questions pertaining to whether a Drug, biologic, device, Diagnostic, product, equipment, procedure, treatment, service, or supply is Experimental/Investigative.

AR 0060-61.

When an employee benefit plan denies an employee's claim for benefits, ERISA requires the plan to provide "adequate notice" of the denial in writing, "setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant" and to afford the employee "a reasonable opportunity" for "a full and fair review" of the denial. 29 U.S.C. § 1133. The Anthem policy provides for several reviews of a coverage decision, as spelled out below. The parties agree that plaintiff has exhausted remedies available through Anthem itself.

III. *Anthem's Review of Plaintiff's Case*

A. *The First Review*

1. *The First Request*

On March 12, 2008, Dr. Vianna and his colleagues sought pre-approval from Anthem for the proposed multivisceral transplant surgery. Indiana University Hospital is part of Clarian Health Partners. The request consisted of Dr. Vianna's letter and Mrs. Reimann's medical records. AR 0362-428. The next day, Anthem referred the request to MCMC, a peer review analysis network, for a review of the medical necessity of the proposed transplant surgery. AR 0429-39. Anthem's request stated that Mrs. Reimann's diagnosis was "metastatic liver cancer, neuroendocrine tumors and carcinoid syndrome," and summarized Dr. Vianna's recommendation and reasoning for the transplant. AR 0436. The request also included Anthem's internal medical policy TRANS.00013, entitled "Small bowel and multivisceral transplant including, small bowel, liver." AR 0435. Anthem's request for review stated that its internal medical policy was included "for your reference only and you are expected to exercise your independent medical judgment in this review." Anthem requested a specialty group of internal medicine and a specialty of hematology and oncology. AR 0430. Anthem asked the outside reviewer to answer the following questions:

> 1. Is there sufficient information about the patient history and the recommended treatment plan to provide a reasoned opinion?

> 2. Has the requested treatment or service been shown to be more beneficial than any available standard treatment or service for this patient? If yes, please base your analysis on any relevant findings published in peer reviewed medical or scientific literature or the published opinions of medical experts or specialty societies. Please take into consideration the safety, efficacy, and appropriateness of the proposed treatment.
>
> 3. If the answer to question 2 is "yes" then is this treatment medically necessary for this patient?

AR 0435.

2. *The First Outside Review*

The first outside reviewing physician concluded that the proposed multivisceral transplant was not medically necessary. The reviewer found that he had sufficient information, and he concluded: "The requested treatment or service has not been shown to be more beneficial than any available standard treatment or service for this patient." AR 0444. As part of his report, the reviewer also certified his independence from both Anthem and the Indiana University physicians, as well as from any other party that might be interested in the result of the review. AR 0445-46. The reviewer provided the following as his rationale:

> According to the policy sent with this review, the diagnosis of metastatic cancer is defined to be an "absolute contraindication" to multivisceral transplant, and this patient has metastatic cancer. Moreover, the patient's diagnoses are not defined by Policy to be among the indications that can be medically necessary for this type of transplant. The major available literature with adequate follow-up consists of case series, and the results of well-controlled randomized studies are not available. The review of Olausson et al concluded "The recurrence-free survival of both multivisceral and liver transplantation related to the time after transplantation (about 20% at five years) despite inclusion of patients with

> higher risk. In conclusion, the critical prognosticators for long-term outcome still remain to be defined. The experience with multivisceral transplantation for patients with endocrine tumors of the pancreatic head is still limited." Thus, the question above asks "if the requested treatment or service [has] been shown to be more beneficial than any available standard treatment or service", and, well controlled randomized studies are not available to conclude that multivisceral transplant will be "more beneficial" than any other available standard.
>
> The NCCN guidelines do describe surgery options for management of metastatic carcinoid tumor, but these include wedge resection or partial hepatectomy and they do not include multivisceral transplant.

AR 0445.

The reference to the "NCCN" guidelines was to the National Comprehensive Cancer Network, a non-profit alliance of 21 national cancer centers. NCCN has developed clinical practice guidelines based on the independent evaluation of available scientific evidence and the expert judgment of its clinicians. See About NCCN, http://www.nccn.org/about/ (last visited Oct. 29, 2008). At least one court has recognized that NCCN is "an expert body in the field of clinical oncology" and that NCCN guidelines "are authoritative in the field." *Zeneca Inc. v. Eli Lilly & Co.*, 1999 WL 509471, *23 (S.D.N.Y. July 19, 1999).

The reviewer's reference to Olausson was to an article entitled *Orthotopic Liver or Multivisceral Transplantation as Treatment of Metastatic Neuroendocrine Tumors*, 13 Liver Transplantation 327 (2007). The article reports on five patients who received multivisceral transplants in Sweden, as well as ten patients who received only liver transplants. The patients who received multivisceral

transplants all had neuroendocrine tumors that were still confined to the liver. (Mrs. Reimann's tumor has metastasized to involve both lobes of the liver, the peripancreatic region, and the small intestine.) Of the five, two died within four months of causes associated with the transplant itself. A third patient died of a recurrent tumor 27 months after the transplant. A fourth patient was alive and tumor-free 12 months after the transplant. The fifth was alive four years after the transplant, though with tumor recurrence and poor renal function. The authors concluded that they had confirmed that liver transplants are "a valuable treatment for individual patients with unresectable liver metastases of neuroendocrine tumors." *Id*. at 332.

With respect to multivisceral transplants for such patients, however, Olausson and his colleagues concluded that the experience "is still too limited for proper evaluation." *Id*. at 333. In light of the Anthem policy definition of medical necessity, that conclusion is powerful, especially because Mrs. Reimann's cancer has metastasized beyond the level of the handful of patients studied in Sweden.

3. *The First Letter to Mrs. Reimann*

On March 21, 2008, Dr. Richard Lane, Anthem's medical director, wrote a letter to Mrs. Reimann denying pre-approval of the proposed transplant surgery. Dr. Lane wrote:

On behalf of Anthem, we want you to understand how your health plan works, so you can get the most from your benefits. In cases where coverage is not approved, we want you to understand why and to know your options.

Based on review of the information available to us by an independent physician consultant with a special interest in multiviseral [sic] transplantation and your health benefit plan, you do not have coverage for the service referenced above, because the physician consultant has determined the following:

Well Controlled randomized studies are not available to conclude that multivisceral transplant will be "more beneficial" than any other available standard.

The National Comprehensive Cancer Network guidelines do describe surgery options for management of metastatic carcinoid tumor, but these include wedge resection or partial hepatectomy and they do not include multivisceral transplant.

Therefore, based on the review of the information provided to us, the clinical judgment of the physician reviewer, and your health benefit plan, the service referenced above is not medically necessary, as defined in your health certificate. Services which are not medically necessary are a benefit exclusion and therefore not a covered benefit.

If you do not agree with this determination, your provider may request a reconsideration. Your provider may submit additional information that might support the necessity of this service, or your provider may request a peer consultation by calling Anthem Transplant Unit at 800-824-0581. Requests for peer consultation and submission of additional information must be received within 10 business days of the date of this letter; after 10 business days, the request will be treated as an appeal.

You have the right to initiate an appeal (often referred to as a grievance) by calling or writing us. If you write a letter, be very specific and enclose any relevant correspondence you may have. Address this letter to the attention of:

Anthem UM Services Inc.
Appeals Department
P.O. Box 37220
Louisville, Kentucky 40233-7220

You may also call an Appeals Specialist at 1-800-325-3377. If you request an appeal and the decision is upheld, you may have additional appeal

> rights. Please see the enclosed additional information regarding the appeals process.
>
> You may have the right to request Anthem to by-pass any internal level of appeal available to you and proceed directly to the external appeal process. Any levels of review that have been bypassed are not later available. If you request to by-pass an internal level of appeal and sign the attached waiver agreeing to do so, Anthem waives any right to assert that you failed to exhaust administrative remedies because you did not file an internal appeal.
>
> You have the right to designate a representative (e.g. your physician) to file an internal appeal or, if available, an external review on your behalf and to represent you in that review.
>
> If you have any questions or concerns, please do not hesitate to call your nurse case manager within the Transplant Department at 800-824-0581, option 3 prompt 8.

AR 0451-52 (emphasis in original).

Dr. Lane's reference in the second paragraph to a consultant "with a special interest in multiviseral [sic] transplantation" is troubling. Because the independent review was anonymous and Anthem received only limited information about the reviewer's qualifications, there is no obvious basis for Dr. Lane's claim.[2]

Dr. Lane's letter of March 21st did not refer to Anthem's internal medical policy, TRANS.00013, which lists metastatic cancer as an "absolute contraindication" for multivisceral transplant. The policy recognizes that multivisceral transplant operations may be a necessary treatment for a specific

[2]The full curriculum vitae of the first reviewer shows that he was well qualified in hematology and oncology, but there is no apparent basis for concluding he had a "special interest" in multivisceral transplants. SAR 0113-21.

subset of patients who have been managed with TPN (intravenous total parenteral nutrition) and who show signs of impending end-stage liver failure, with five-year survival rates of 30 to 50 percent. AR 0154. The policy's list of "absolute contraindications" for such transplants – including metastatic cancer – was taken from the American Society of Transplantation's Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation issued in 2001. See AR 0153.

B. *The Second Review*

1. *The Second Request*

On behalf of Mrs. Reimann, Dr. Vianna and Clarian appealed to Anthem for further review on April 1, 2008. This second request consisted of a letter from Dr. Vianna dated April 1, 2008, a letter from Dr. Keith D. Lillemoe, and plaintiff's medical records. AR 0168-240. Dr. Vianna's letter explained that he had received the first reviewer's comments and had asked Dr. Lillemoe to review the case. Dr. Lillemoe is the chief of surgery at Indiana University and the editor of Annals of Surgery. Dr. Lillemoe is a world authority on neuroendocrine and pancreatic tumors.

Dr. Vianna's April 1st letter stated:

> I have received the comments on Reimann's case by the first reviewer. Even though we have already very carefully evaluated her options we

decided to submit Ms. Reimann's case to be evaluated by Dr. Keith Lillemoe. Dr. Lillemoe is a much respected hepatobiliary surgeon and chief of surgery at Indiana University. He is also the editor of *Annals of Surgery*, the most respected journal in the field of surgery. He is considered a world authority in neuroendocrine and pancreatic tumors. His evaluation and letter are included.

Case Summary

Ms. Reimann is a 59-year old female diagnosed with a carcinoid tumor that involves both lobes of her liver, duodenopancreatic nodes and bowel. She has come to Indiana University School of Medicine for evaluation of [this] condition and recommendations for therapy. The best treatment for this tumor is surgical resection. In order to perform a complete resection of this cancer, which affords the best chance of cure, it may be necessary to resect not only the liver but also the bowel and pancreas. In that way, all the lymphatic tissue and nodes would be removed as well. If it becomes necessary to remove all of these organs in the process of removing this patient's tumor, we propose an immediate multivisceral transplant including the liver, pancreas and small bowel in order to simultaneously cure Ms. Reimann's disease and restore her normal physiology. The use of multivisceral transplantation in the surgical management of neuroendocrine tumors has been described and, in appropriately selected patients, has a survival rate similar to that for other transplant patients without cancer. Adult survival after primary multivisceral transplant at our center is 89%. (SRTR data – Jan. 2008).

Pancreatic endocrine (or neuroendocrine) tumors are uncommon neoplasms that share a number of features. Histologically they are classified as apudomas and share cytochemical features with melanoma, pheochromocytoma, carcinoid tumors, and medullary thyroid carcinoma. All APUD (amine precursor uptake and decarboxylation) neoplasms have the capacity to synthesize and secrete polypeptide products that have specific endocrine hormone activity. Pancreatic endocrine tumors are vascular tumors with similar radiographic appearances and metastatic patterns of spread (primarily to regional lymph nodes and liver). In the absence of carcinoid syndrome, primarily small intestinal carcinoid tumors are managed similar to small bowel adenocarcinoma. Given the high rate of synchronous lesions, compulsive search for lesions are mandatory. As with other apudomas, malignancy is only defined by the presence of metastases at operation or by imaging studies. Complete surgical resection is the only curative modality for patients with carcinoid, and the success of the operation is contingent on establishing the correct diagnosis and performing the appropriate resection. It is critical to remove all viable tumor to optimize the chance for cure.

> Due to its biologically less aggressive nature, neuroendocrine tumors and metastatic lesions may represent a good indication for transplantation. Liver transplantation and multivisceral transplantation have been performed in situations [where] the root of the mesenteric vessels or liver metastasis are present. We have listed the relevant recent literature on this topic in the references that follow (1, 2, 3, 4, and 5).
>
> Like many cancers, neuroendocrine tumors are slow to metastasize and frequently metastasize to the liver only. However, unlike other malignancies, these tumors can be limited to their primary location or to the liver for protracted periods of time. This provides a window for definitive treatment. Unfortunately, like all cancers, these tumors will eventually progress and are ultimately fatal if left inadequately treated. In Ms. Reimann's case, we feel that primary resection with multivisceral transplant backup is the optimal treatment for her tumor, providing her the greatest chance of cure and long-term survival.
>
> Our facility has been approved as a Medicare Center of Excellence in the field of intestinal and multivisceral transplantation. We have performed 46 intestinal and multivisceral transplants in adults since 2003 with an 89% overall adult multivisceral survival which makes us one of the most successful programs in the world. We strongly believe that Ms. Reimann has an excellent chance of being cured from her disease with a complete resection and possible multivisceral transplant. We appreciate your careful and thoughtful consideration of Ms. Reimann's request for insurance approval for this potentially life-saving treatment.

AR 0170-72 (emphasis in original).

Dr. Lillemoe wrote:

> At present, there is no resection therapy that I feel could be successfully offered to the patient which does not include the potential for a multi-visceral transplant. It would appear to me that the liver disease itself is too extensive to be managed with any form of major hepatic resection and even if it was, there would still be extrahepatic disease in both the peripancreatic lymph nodes as well as in the lymphatic channels draining the primary tumor.
>
> In my opinion, only a total abdominal organ resection with multi-visceral transplant would provide a potentially "curative" resection. These carcinoid tumors are well known for their slow indolent however, progressive course and in my opinion are among the most suitable forms of

> malignancy for which massive visceral resection and transplantation can be considered an appropriate option.

AR 0173.

Anthem referred the appeal to AMR (Advanced Medical Reviews), another outside reviewer. For a specialty match, Anthem requested "surgeon – experience/knowledge." The request said: "use TRANS.00013 for review of intestinal transplant." AR 0151. Unlike the first request, which was phrased only in terms of medical necessity and said the internal Anthem medical policy was provided only for informational purposes, Anthem's second request asked: "Based on Wellpoint [Anthem] medical policy, is the transplant of internal multi considered experimental/investigational?" AR 0149. The second request also asked: "Based on Wellpoint medical policy, is the transplant of internal multi medically necessary?" *Id*.

2. *The Second Review*

The second reviewer provided a report on April 14, 2008. At the top of the report, the reviewer said "no" as to whether the proposed transplant was experimental or investigational and "no" as to whether the proposed transplant was medically necessary. AR 0149. The rationale, however, said both that the proposed transplant surgery was experimental and investigational and was not medically necessary. The report's rationale stated in full:

Question 1: Yes Experimental/Investigative

According to Wellpoint General Transplant Selection Criteria:

Absolute Contraindications for Transplant Recipients: Metastatic Cancer. This patient has metastatic cancer tumor in her liver/lymph nodes.

Question 2: No, this patient does not meet all the criteria for medical necessity for multivisceral transplant

a) Meets criteria for small bowel transplant: No

1) Short bowel syndrome: No

2) Intestinal failure/failed parentential nutrition: No

3) Meets general patient selection criteria: No (metastatic disease)

b) Has overt or imminent liver failure: No (Calculated MELD Score of only 6: Needs greater than 15)

c) Needs addition abdominal organs due to failure or anatomic requirements: Yes (pancreas)

AR 0149. Thus, the second outside review seems to have consisted of applying Anthem's internal policy, which deems metastatic cancer an absolute contraindication for multivisceral transplants, based on the guidelines issued by the American Society of Transplantation.

3. *The Second Letter to Mrs. Reimann*

Anthem responded to the appeal orally on or before April 18, 2008 (see AR 0144-45) and responded in writing on April 29, 2008 based on the second outside

review. In a letter to Indiana University Hospital, with copies to Mrs. Reimann and Dr. Vianna, Anthem appeal specialist Brian Gentile wrote:

> Thank you for giving Anthem UM Services, Inc. ("Anthem"), the opportunity to review your Standard Appeal received in our office on April 1, 2008, for the above referenced member. It is Anthem's understanding that you are appealing the denial for the Operations On The Digestive System; Other Operations on Intestine; Other Operations on Intestines; Transplant of Intestine.
>
> Anthem has carefully considered the submitted medical information, the applicable terms of the member's health plan document and the WellPoint (Anthem is a subsidiary of WellPoint) Medical Policy TRANS:00013 for Small Bowel and Multivisceral Transplant Including Small Bowel/Liver. However, based on the review by Anthem's Physician Consultant, who is Board Certified and specializes in General Surgery, Anthem is unable to approve your request to change the original decision. Our physician's review of the available information indicated that this patient does not meet all the criteria for medical necessity for multivisceral transplant.
>
> A) Meets criteria for small bowel transplant: No
>
> 1) Short bowel syndrome: No
> 2) Intestinal failure/failed parenteral nutrition: No
> 3) Meets general patient selection criteria: No (metastatic disease)
>
> B) Has overt or imminent liver failure: No (Calculated MELD Score of only 6; Needs greater than 15)
>
> Therefore, the previous denial of coverage is upheld based upon the medical necessity exclusion within the members' health plan document.
>
> The screening criteria used for the review of this case were the WellPoint (Anthem is a subsidiary of WellPoint) Medical Policy TRANS:00013 for Small Bowel and Multivisceral Transplant Including Small Bowel/Liver. A copy of the applicable guidelines can be obtained by writing to the above address.
>
> The member may request a copy of the plan language by writing to the above address.
>
> Please note that this letter serves to inform you that this decision is final and all levels of Anthem's appeal process have now been exhausted. If all

> appeal rights have been exhausted and you disagree with the company's decision, you have the right to file a complaint with the Ohio Department of Insurance at Ohio Department of Insurance, Market Regulation Division Complaint Unit, 2100 Stella Court, Columbus, Ohio 43215-106 or call 614-644-6428.
>
> Although Anthem realizes that this is not the answer you had hoped for, we appreciate the opportunity to review your request and explain our position.

AR 0247-48.[3]

Gentile's letter referred specifically to Anthem's internal medical policy, TRANS.00013, and indicated that a copy was available upon request. See 29 C.F.R. § 2560.503-1(g)(1)(v)(A) (requiring such provision of internal policies). Although the second reviewer had concluded that the transplant surgery would be experimental or investigational and was not medically necessary, Gentile's letter referred only to the more general medical necessity exclusion. He did not mention anything specifically about the surgery being experimental or investigational. Anthem apparently received information that the AMR reviewer was a "general surgeon" who was "experienced in this surgery." AR 0144.[4]

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[3]The reference to the *Ohio* Department of Insurance is an unexplained mistake. In any event, as discussed below, the letter should have told Mrs. Reimann that she had a right to file a civil action in federal court under ERISA.

[4]Anthem has filed a second supplemental administrative record with detailed curricula vitae of the outside reviewers. That record shows that the second reviewer is the chief of transplantation at a major university medical center, former director of kidney and pancreas transplantation, and a long-time professor of transplant surgery with numerous peer-reviewed publications. SAR 0017-48.

C. *The Third Review*

1. *The Third Request*

In response to the second denial, plaintiff filed this lawsuit on June 18, 2008 and moved for a preliminary injunction ordering Anthem to cover the costs of the proposed transplant surgery. The case was pending before another district judge at that time. After some preliminary skirmishing, the parties agreed in early August to submit the case to an independent review organization (IRO) on terms under which (a) Anthem's medical policy would not be treated as binding on the reviewer, and (b) Anthem agreed that it would be bound by a reviewer's conclusion that the proposed transplant surgery should be covered.

On August 6, 2008, Anthem wrote to an IRO called IMEDECS to request a further external review of Mrs. Reimann's case. The request stated that Anthem had denied coverage based on a finding that the proposed surgery was experimental or investigational and not medically necessary. AR 1098. Anthem requested review by a surgeon with experience and expertise with intestinal and multivisceral transplant procedures. *Id*. The request included extensive records from Anthem, and a package of materials prepared by plaintiff's attorney, with affidavits from Dr. Vianna and Dr. Lillemoe, as well as Dr. Andreas Tzakis, another leading surgeon in this field. See AR 469-1096.

Plaintiff included in the materials three articles on multivisceral transplants, all reporting on experience at the University of Miami, where Dr. Tzakis practices. The University of Miami is one of the leading centers for intestinal transplant surgery.

By the time these materials were assembled, plaintiff, her attorneys, and her doctors knew that Anthem and any independent reviewer would be vitally interested in any reports on the use of multivisceral transplants to treat patients like Mrs. Reimann, who had cancer that had metastasized. The articles are perhaps most compelling for what they do not show. They do not show even unsuccessful multivisceral transplants for any patient comparable to Mrs. Reimann, with cancer that had metastasized beyond the liver.

The first article, by Nishida and others, reports on the experience with 150 multivisceral transplants at the University of Miami. AR 1041. None of those transplants were reported to involved patients with cancer, let alone with cancer that had metastasized. The second article, by Tzakis and others, reported on a host of surgical issues involved with this very challenging and dangerous transplant operation. AR 1057. The article also did not describe any use of the surgery to treat cancer.

The third article, by Moon and others, reported on 21 intestinal transplants for patients with various types of neoplastic diseases, including some malignant

tumors. Among those patients, five had multivisceral transplants that included the liver. AR 1072. Two patients had neuroendocrine tumors.

One patient (Patient 11) had neuroendocrine tumors-carcinoid that involved the mesentery (the membrane that attaches the intestines to the abdominal wall) and adjacent lymph nodes, in addition to metastasis to the liver, but there was no evidence of extraperitoneal metastasis. AR 1075. The operation removed all of the tumor, but the patient had a recurrence of carcinoid tumor in her breasts and ovary eight months after the transplant. She died of advanced carcinoid tumor 24 months after the transplant. Patient 16 had another form of neuroendocrine tumor called VIPoma (originating in the pancreas) that had metastasized to the liver. That patient was alive and doing well 23 months after the transplant.

After describing these two patients, the authors reported: "In our experience, allograft[5] abdominal organ cluster transplantation would be indicated for neuroendocrine tumors with reasonable clinical outcome, when there is no other feasible treatment option. Biological behavior of each neuroendocrine tumor needs to be studie[d] further." AR 1076. On the larger issue, Moon and his colleagues recognized that among all types of neuroendocrine tumor, positive clinical outcomes were well-reported for carcinoid tumor treated by

[5]An "allograft" transplant is from another member of the same species who is not genetically identical to the recipient.

transplantation of the liver alone. AR 1075. Even with metastasis within the liver, liver transplant produced a survival rate of approximately 60 percent. *Id*.

More pertinent to Mrs. Reimann's case, the authors wrote: "However, there is no study yet which revealed more radical resection such as abdominal organ cluster transplantation has shown better results than liver transplant alone for this type of tumor." *Id*. And again, Mrs. Reimann's cancer has metastasized beyond the liver, unlike the patients studied by Moon and his colleagues, apart from Patients 11 and 16.

Anthem asked the third reviewer to answer the following questions:

> Is the intestinal and multivisceral transplant procedure, as it is proposed in the patient's case, experimental/investigative?
>
> Is the intestinal and multivisceral transplant procedure, as it is proposed in the patient's case, experimental/investigative according to the enclosed health insurance certificate?
>
> If the intestinal and multivisceral transplant procedure is not experimental/investigative, is it medically necessary in the patient's case?
>
> Has sufficient information been provided to render a medical opinion?
>
> Do you affirm or overturn Anthem's decision to disallow coverage for the patient's proposed intestinal and multivisceral transplant procedure?
>
> Do you have experience or expertise with intestinal and multivisceral transplants, as proposed in the patient's case?

AR 1098-99.

2. *The Third Review*

IMEDECS reported that the third review was carried out by a doctor who is board certified in surgery, completed a residency in general surgery and a fellowship in pediatric surgery, and another fellowship in transplant surgery. The reviewer currently serves as assistant director of transplantation services and attending surgeon treating adults and children. The reviewer is also a member of the American College of Surgeons, the American Society of Transplantation, and the Society of Critical Care Medicine. The reviewer also serves as a journal reviewer and is "well-published in peer reviewed literature." AR 1101.

The third reviewer concluded that the proposed multivisceral transplant is not medically necessary and upheld the denial of coverage. The reviewer explained his reasoning, which showed extensive familiarity with the field, including the expertise of plaintiff's doctors at Indiana University:

> Multivisceral transplantation is being performed more commonly in the United States with a few institutions including the petitioner being leaders in this modality. Short-term survival of these cases can approach that of liver transplant alone and are excellent in many cases.
>
> Transplantation of the liver for neuroendocrine tumors including carcinoid is recognized as appropriate and medically necessary when involving the liver in a way that is considered not amenable to hepatic reaction. The liver transplant community has not accorded this tumor the same medical urgency status as that of hepatocellular carcinoma, refusing to increase MELD for carcinoid as a matter of routine. Short-term survival of carcinoid tumors even when extensive in the liver is better without liver transplantation. Intermediate and long-term survival may not be better with liver transplantation over other therapies.

> Multivisceral abdominal organ transplantation for carcinoid tumor that extend beyond the liver does not have enough support in the medical literature to be considered acceptable medical therapy. This particular patient has advanced disease which may in fact be extended into the chest, based upon the most recent octreotide scan.
>
> The Health Insurance Certificate language on page M-39 characterizes the proposed therapy as not meeting clinical coverage guidelines. Moreover, on page 44 of the same document, language addressing the scientific evidence does support an Experimental/Investigational designation by the plan because 1) scientific evidence of this therapy is not conclusory as to its benefit, 2) there is not evidence that the proposed therapy improves net health outcome for this population, 3) the service has not been shown to be beneficial. On page M-79 of the same document any treatment determined by the plan to be unproven is also classified as Experimental/Investigational. Removal (and immediate transplant) of the liver, stomach, pancreas and intestine for the treatment of metastatic carcinoid can only be considered unproven. On page M-80 of this document, under 'definitions' "medically necessary" determination does rest with the Plan.

AR 1103-04. The critical conclusion is in the third paragraph: that the multivisceral transplant for treatment of cancer that has metastasized beyond the liver does not have enough support in the medical literature to be considered accepted medical therapy.

3. *The Third Letter to Mrs. Reimann*

On August 11, 2008, IMEDECS wrote directly to Mrs. Reimann to report that the reviewer had upheld the decision. AR 1101 (including copy of report). Anthem wrote to her the same day with a more detailed cover letter that quoted the relevant plan language and described the reviewer's credentials and

conclusion. AR 1107-08. The August 11th letter from Anthem did not offer advice as to the right to sue under ERISA, but this lawsuit was already pending.

D. *The Fourth Review*

1. *The Fourth Request*

In opposing plaintiff's motion for preliminary injunction, Anthem relied on the first, second, and third reviews. Dkt. No. 39 (filed August 14, 2008). In her reply brief, filed August 27, 2008, Mrs. Reimann argued that IMEDECS was not properly certified by the Indiana Department of Insurance as an independent review organization and that its review therefore could not support the denial of coverage. Pl. Reply 6-7. Plaintiff submitted an affidavit from Danielle Fuller, a review agent specialist with that department. Fuller testified that she had reviewed the pertinent files and found that, although IMEDECS had previously been registered and certified as an independent review organization, it was not properly registered and certified in Indiana in 2008. Pl. Reply, Ex. 5. On July 16, 2008, the department had issued a letter to IMEDECS requesting information about its certification status, but IMEDECS had not responded as of August 14, 2008.

Anthem responded to this development in two ways. First, Anthem submitted a surreply brief with an affidavit and supporting documentation from IMEDECS' director of operations Deahna Montaque. Montaque testified that

IMEDECS had been properly certified in Indiana in 2005 when it received a letter from the Indiana department extending the certification indefinitely because the department was revising the process for recertification. The letter told IMEDECS that when the process was complete, the department would notify IMEDECS and give it 30 days to provide any information needed for recertification. Def. Surreply, Ex. 1, ¶ 8. IMEDECS did not hear anything further on the subject until it received the July 16, 2008 letter from Fuller stating that its Indiana certification had expired on December 31, 2007. On August 14, 2008 (the same day that Fuller signed her affidavit), IMEDECS responded. Anthem argued in its surreply brief that the Indiana department should be deemed estopped from treating IMEDECS as if its certification had expired and that Anthem had reasonably relied on the IMEDECS review.

Second, on September 3, 2008, Anthem submitted Mrs. Reimann's case for a fourth review with a different independent review organization, NMR (National Medical Reviews). Anthem provided the same package of information it had provided to IMEDECS and asked the same questions. SAR 0002-03.

2. *The Fourth Review*

NMR submitted the case to a physician who is board certified in medical oncology "with experience/qualifications in the treatment of these types of

patients." SAR 007. This fourth reviewer upheld the denial of coverage. After detailing the materials submitted, the reviewer explained his reasoning:

> This 59-year-old woman has Carcinoid involving both lobes of the liver, duodenopancreatic nodes and bowel.
>
> Carcinoid tumors are relatively rare, and in general, slow growing. When more malignant in behavior they are called neuroendocrine tumors (NET). They can be "non-functioning" tumors, presenting as masses, or they can [secrete] a variety of substances that can cause symptoms known as "Carcinoid syndrome".
>
> There is wide consensus on how these treatments should be approached as evidenced by a number of guidelines that have been published. While liver resection and transplantation may be an option for some patients from whom all extrahepatic tumours and metastases have been removed and in whom no recurrence of extrahepatic tumour is expected. Recurrences are very common.
>
> In general, cancer that has spread is considered incurable, except in some chemo-sensitive cancers like lymphomas. To attempt to resect all visible disease for cure and to make it possible to do so by transplanting intestine is a very aggressive approach that requires credible confirmation in studies before being adopted. The intestinal transplant registry does not include Carcinoid tumors in its listing of cases for which intestinal transplantation has been performed as of 2003.
>
> A small bowel transplant is typically performed in patients with short bowel syndrome. Etiologies of short bowel syndrome include volvulus, atresia, necrotizing enterocolitis, Crohn's disease, gastroschisis, thrombosis of the superior mesenteric artery, desmoids tumors, and trauma. Patients with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become dependent upon total parenteral nutrition (TPN). It is not clear that intestinal transplantation is justified for Carcinoid tumors that grow slowly and often have a survival measured in years. In a recent publication of one center's experience, there were 25 auto or allograft transplantations in 21 patients for desmoids tumor (14), neuroendocrine tumor (2), Adenocarcinoma (2), hemangioma (1), lymphoma (1), and solid pseudopapillary carcinoma.
>
> There were 11 graft losses; mortality with functioning graft (6); ischemic necrosis (2), and arterial thrombosis (1) during 31 days of mean follow-up. Seven patients died because of recurrent neoplasm and

transplant related complications. Six patients experienced recurrent disease; Three Dermoid tumor (14), two Adenocarcinoma (2/2), and one neuroendocrine tumor (1/2). Among 14 survivors, two need parenteral nutrition or intravenous hydration.

1. Is the intestinal and multivisceral transplant as it is proposed in this patient's case experimental/investigative?

Yes, the intestinal and multivisceral transplant as it is proposed in this patient's case is experimental/investigative.

2. Is the intestinal and multivisceral transplant as it is proposed in this patient's case experimental/investigative according to the enclosed health insurance certificate?

Yes, the intestinal and multivisceral transplant as it is proposed in this patient's case is experimental/investigative according to the enclosed health insurance certificate.

3. If not experimental/investigative, is it medically necessary?

No, the intestinal and multivisceral transplant procedure is not medically necessary.

4. [Has] sufficient information been submitted to render a medical opinion?

Yes, sufficient information was submitted to render a medical opinion.

5. Do you affirm or overturn Anthem's decision to disallow coverage for the patient's proposed intestinal and multivisceral transplant procedure?

I affirm Anthem's decision to disallow coverage for the patient's proposed intestinal transplant procedure.

6. Do you have experience or expertise with intestinal and multivisceral transplants as proposed in this patient's case?

As a medical oncologist, I treat Carcinoid tumors and have experience in determining appropriateness of current standards in their treatment. As per http://www.intestinaltransplant.org/centres.htm, there are only 29 centers in the United States that perform such transplants.

SAR 0014-15.

Conclusions of Law

I. *Standard of Review*

A. *Anthem's Reservation of Discretionary Authority*

The parties disagree as to whether the court should review Mrs. Reimann's ERISA claim *de novo* or apply the abuse of discretion standard. In ERISA claims, the plan language determines the standard of review that will apply. "Absent clear language to the contrary, plans are read to provide for searching judicial review of benefits determinations: plenary review of the administrator's interpretation of the facts and plan, fortified by the district court's discretionary authority to hear evidence that was not presented in the administrative process." *Patton v. MFS/Sun Life Financial Distribs., Inc.*, 480 F.3d 478, 485 (7th Cir. 2007), citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 110-15 (1989). The employee thus presumptively has a right to *de novo* review by way of a court's "informed and independent judgment" on her claim for benefits, informed by evidence as the court thinks necessary, and fully independent of the plan administrator's findings and reasoning. *Id*.

However, a plan can provide, and many do provide, for more deferential judicial review of benefits determinations by including language that "gives the

administrator or fiduciary discretionary authority to determine eligibility for benefits." *Diaz v. Prudential Ins. Co. of America*, 424 F.3d 635, 636-37 (7th Cir. 2005), citing *Firestone Tire*, 489 U.S. at 115. The language must possess "requisite if minimum clarity" indicating that the administrator "not only has broad-ranging authority to assess compliance with pre-existing criteria, but also has the power to interpret the rules, to implement the rules, and even to change them entirely." *Diaz*, 424 F.3d at 637, 639, citing *Herzberger v. Standard Ins. Co.*, 205 F.3d 327, 331 (7th Cir. 2000).

Anthem has overcome the presumption of *de novo* review by including clear language in its policy giving it discretionary authority to interpret and apply the policy. Under the heading "Reservation of Discretionary Authority," the Hillcrest Health Certificate states in part:

> The Plan, or anyone acting on Our behalf, shall determine the administration of benefits and eligibility for participation in such a manner that has a rational relationship to the terms set forth herein. However, We, or anyone acting on Our behalf, has [sic] complete discretion to determine the administration of your benefits. Our determination shall be final and conclusive and may include, without limitation, determination of whether the services, care, treatment or supplies are Medically Necessary, Experimental/Investigative, whether surgery is cosmetic, and whether charges are consistent with Our Maximum Allowable Amount.

AR 0092. Anthem further reserved the rights to construe the contract, to determine all questions arising under the Health Certificate, and to make, establish, and amend the rules, regulations, and procedures concerning the

interpretation and administration of the provisions of the Health Certificate. See *id*. This is a clear reservation of discretionary authority.

Thus, the court "must review a denial of benefits deferentially, asking only whether the plan's decision was arbitrary or capricious." *Hess v. Reg-Ellen Mach. Tool Corp. Employee Stock Ownership Plan*, 502 F.3d 725, 727 (7th Cir. 2007). Under the arbitrary and capricious standard, an administrative decision will be overturned only if it is unreasonable. *Id*. Absent unusual circumstances, such as fraud or bad faith, a decision to deny benefits is not deemed arbitrary and capricious if it is possible to offer a reasonable explanation for that decision based on the evidence. See *Trombetta v. Cragin Fed. Bank for Sav. Employee Stock Ownership Plan*, 102 F.3d 1435, 1438 (7th Cir. 1996); see also *Mers v. Marriott Int'l Group Accidental Death and Dismemberment Plan*, 144 F.3d 1014, 1021 (7th Cir. 1998) (stating that courts are not to set aside a plan administrator's denial of benefits that is "based on a reasonable interpretation of the plan documents"). A decision is arbitrary and capricious "only when the decisionmaker 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence . . . or is so implausible that it could not be ascribed to difference in view or the product of . . . expertise.'" *Trombetta*, 102 F.3d at 1438, quoting *Pokratz v. Jones Dairy Farm*, 771 F.2d 206, 209 (7th Cir. 1985). The arbitrary and capricious standard of review requires the court to evaluate "the impartiality of the decisionmaking body, the complexity of the issues, the process

afforded the parties, the extent to which the decisionmakers utilized the assistance of experts where necessary, and finally the soundness of the fiduciary's ratiocination." *Chalmers v. Quaker Oats Co.*, 61 F.3d 1340, 1344 (7th Cir. 1995); see also *Hughes v. Life Ins. Co. of North America*, 112 F. Supp. 2d 780, 793 (S.D. Ind. 2000) (applying *Chalmers* factors).

B. *Matuszak Is Not Comparable*

In her reply brief, Mrs. Reimann relies on *Matuszak v. Torrington Co.*, 927 F.2d 320 (7th Cir. 1991), to argue that *de novo* review is mandated because Anthem changed its reasons for denying her claim. Pl. Reply 8-10. In *Matuszak*, the employer announced, years after the fact, that employees would be eligible for plant closing benefits if they were actively working at the plant on the date the plant closing was announced. In litigation, the employer abandoned this position and agreed that employees who were on layoff on the date of the plant closure announcement could be eligible for benefits. *Matuszak*, 927 F.2d at 322. The Seventh Circuit applied *de novo* review because "*no* plan can provide discretion to deny benefits for reasons identified only years after the fact," and by footnote remarked that the fact the employer had abandoned its original reason for denying benefits was highly relevant to the court's determination that *de novo* review applied. *Id*. at 322 & n.3. Otherwise, ERISA's disclosure requirement would be "emasculated." *Id*. at 323.

In this case, there has been no similar shift in position. The first two denials described the multivisceral transplant as "not medically necessary" because there was not sufficient evidence to evaluate the procedure for patients as sick as Mrs. Reimann. See AR 0451, 0247. The third and fourth denials both said the procedure would be experimental and/or investigatory and would not be medically necessary.

Under the plan language, "experimental/investigative" treatments are only a subset of those that are "not medically necessary." See AR 0096 ("Medically Necessary/Medical Necessity – An intervention that is or will be provided for the diagnosis, evaluation and treatment of a condition, illness, disease or injury and that is determined by Us to be: . . . Not Experimental/Investigative."). The broader definition of "medically necessary" also includes the requirement that the proposed treatment be "[k]nown to be effective, as proven by scientific evidence, in materially improving health outcomes." *Id.* These are two sides of the same coin. "Experimental" is a more specific description of a treatment that Anthem determined to be not "medically necessary." Also, unlike the situation in *Matuszak*, these terms were fully disclosed in Mrs. Reimann's Health Certificate, and their definitions were not drafted after the fact. In Mrs. Reimann's case, "experimental" is not a new or contradictory explanation for Anthem's decision to deny coverage sufficient to overcome Anthem's reservation of discretionary authority in Mrs. Reimann's policy. The court must apply the abuse of discretion standard of review.

C. *Impact of Metropolitan Life Ins. Co. v. Glenn*

On June 19, 2008, the Supreme Court decided *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. —, 128 S. Ct. 2343 (2008). *Glenn* addressed how a plan administrator's financial conflict of interest should affect review under the abuse of discretion standard. *Glenn* held that such a conflict should be weighed as "a

factor in determining whether there is an abuse of discretion." 128 S. Ct. at 2348, quoting *Firestone Tire*, 489 U.S. at 115. The *Glenn* Court specifically disavowed any change in the applicable standard of review from deferential to *de novo*, noting that trust law, on which the Court's reasoning was based, "continues to apply a deferential standard of review to the discretionary decisionmaking of a conflicted trustee, while at the same time requiring the reviewing judge to take account of the conflict when determining whether the trustee, substantively or procedurally, has abused his discretion." *Id*. at 2350. The *Glenn* Court also stated that it did not "believe it necessary or desirable for courts to create special burden-of-proof rules . . . focused narrowly upon the evaluator/payor conflict." *Id*. at 2351.

Instead, the *Glenn* Court held that reviewing courts should continue to take account of several different considerations, of which a conflict of interest is one, and any one factor could act as a tiebreaker when the other factors are closely balanced. 128 S. Ct. at 2351. The Court wrote:

> The conflict of interest at issue here, for example, should prove more important (perhaps of great importance) where circumstances suggest a higher likelihood that it affected the benefits decision, including, but not limited to, cases where an insurance company administrator has a history of biased claims administration. It should prove less important (perhaps to the vanishing point) where the administrator has taken active steps to reduce potential bias and to promote accuracy, for example, by walling off claims administrators from those interested in firm finances, or by imposing management checks that penalize inaccurate decisionmaking irrespective of whom the inaccuracy benefits.

Id. (internal citations omitted).

D. *Procedural Errors Under § 1133*

Mrs. Reimann argues that Anthem committed several procedural errors in its reviews of her claim, that these errors violated ERISA, and that the appropriate remedy for these errors is a reversal of Anthem's denial of her request for coverage. Procedurally, ERISA requires that

> every employee benefit plan shall:
>
> (1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and
>
> (2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

29 U.S.C. § 1133. Regulations set forth the following requirements for the notice of an adverse benefit determination:

> The notification shall set forth, in a manner calculated to be understood by the claimant:
>
> (i) The specific reason or reasons for the adverse determination;
>
> (ii) Reference to the specific plan provisions on which the determination is based;
>
> (iii) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;
>
> (iv) A description of the plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review;

> (v) In the case of an adverse benefit determination by a group health plan or a plan providing disability benefits,
>
> > (A) If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request; or
> >
> > (B) If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.

29 C.F.R. § 2560.503-1(g)(1).

In assessing the notice that a plan has provided regarding an adverse benefit determination, "substantial compliance" with the applicable regulations is sufficient. *Hackett v. Xerox Corp. Long Term Disability Income Plan*, 315 F.3d 771, 775 (7th Cir. 2003), citing *Halpin v. W. W. Grainger, Inc.*, 962 F.2d 685, 690 (7th Cir. 1992). ERISA and its accompanying regulations require that specific reasons for denial be communicated to the claimant and that the administrator "afford the beneficiary an explanation of the denial of benefits that is adequate to ensure meaningful review of that denial." *Halpin*, 962 F.2d at 689-90. Whether the administrator's procedures substantially complied with the statute and regulations is a fact-sensitive inquiry. The focus is on whether the beneficiary was provided with a statement of reasons that allowed a clear and precise

understanding of the grounds for the administrator's position sufficient to permit effective review. *Hackett*, 315 F.3d at 775; *Halpin*, 962 F.2d at 690, 694. To meet the standard of substantial compliance, "the administrator must weigh the evidence for and against [the denial of benefits], and within reasonable limits, the reasons for rejecting evidence must be articulated if there is to be meaningful appellate review." *Halpin*, 962 F.2d at 695.

II. *The Procedural Challenges*

Mrs. Reimann raises a host of procedural challenges to Anthem's handling of her claim, arguing that individually and in sum the alleged violations show that Anthem abused its discretion in denying her claim. All of these challenges are subject to the substantial compliance standard. As explained below, the court rejects most of the challenges. And although there were some procedural errors, those errors either did not cause any substantive harm or have already been remedied by Anthem. None of the errors call for the remedy that Mrs. Reimann seeks.

A. *Appropriate Specialists?*

First, Mrs. Reimann argues that the outside doctors who reviewed her case for Anthem were not specialists in multivisceral transplant operations or neuroendocrine tumors and therefore were not qualified to render an opinion on her claim. In deciding an appeal of an adverse benefit determination that is based in whole or in part on medical judgment, the administrator must consult with a health care professional who has appropriate training and experience in the field. 29 C.F.R. § 2560.503-1(h)(3)(iii). Where the administrator has relied on independent expert advice in making its decision, the court will "respect" that decision if the administrator investigated the expert's qualifications, provided the expert with complete and accurate information, and determined that reliance on the expert's advice was reasonably justified under the circumstances. See *Hightshue v. AIG Life Ins. Co.*, 135 F.3d 1144, 1148 (7th Cir. 1998).

To provide an extra layer of independence, Anthem did not select the outside reviewers. It contracted with MCMC, AMR, IMEDECS, and NMR, which each acted as a clearing-house. Anthem made its requests for review and delegated to those clearing-houses the final selections of the appropriate reviewers. As part of the reports, the clearing-houses provided summaries of the reviewers' qualifications.

For the first review by MCMC, Anthem requested a specialty group of internal medicine and a specialty group of hematology and oncology. AR 0430. Anthem was advised that the first reviewer is board certified in internal medicine, hematology, and oncology. AR 0446. For the second review by AMR, Anthem requested a "Surgeon/Experienced Knowledge" without specifically requesting a physician with training or experience in multivisceral transplants or neuroendocrine tumors. AR 0260. Anthem was advised that the second reviewer is a general surgeon. AR 0150. A multivisceral transplant is one of the most complex and dangerous surgeries in modern medicine, performed by highly specialized doctors after years of training in transplant surgery. The idea that a general surgeon would be suitable for reviewing the case seems surprising, and Mrs. Reimann raised that challenge.

Anthem has supplemented the administrative record with the full curricula vitae of the four reviewers, which it obtained (with help from the court) from the clearing-houses as part of this lawsuit. Those more complete records show that all of the reviewers actually had excellent credentials for reviewing Mrs. Reimann's case. The "general surgeon," for example, is actually the chief of transplantation at a major university medical center and has taught transplant surgery for many years. SAR 0017-18.

Mrs. Reimann has objected to Anthem's effort to supplement the record with the detailed credentials because the information was not available to Anthem

when it actually made its decisions. She also points out that she had requested this information from Anthem several months ago, though Anthem filed it with the court as soon as it obtained the information. Mrs. Reimann relies on some of the many ERISA cases holding that judicial review under the "abuse of discretion" standard generally must be limited to the administrative record before the plan administrator. Dkt. 52 at 4, citing *Hess v. Hartford Life & Accident Ins. Co.*, 274 F.3d 456, 462-63 (7th Cir. 2001), and *Perlman v. Swiss Bank Corp. Comprehensive Disability Protection Plan*, 195 F.3d 975, 982 (7th Cir. 1999). When a plan grants broad discretion to a plan administrator to interpret the plan and make benefit determinations, rendering its determinations subject only to deferential "arbitrary and capricious" review, discovery outside of the administrative record is generally not permitted. See *Vallone v. CNA Fin. Corp.*, 375 F.3d 623, 629 (7th Cir. 2004), citing *Perlman*, 195 F.3d at 981-82 ("Deferential review of an administrative decision means review on the administrative record."). "Like a suit to challenge an administrative decision, a suit under ERISA is a review proceeding, not an evidentiary proceeding." *Semien v. Life Ins. Co. of North America*, 436 F.3d 805, 815 (7th Cir. 2006), quoting *Doe v. Blue Cross & Blue Shield United of Wisconsin*, 112 F.3d 869, 875 (7th Cir. 1997).

The court overrules plaintiff's objection to the supplemental record with the more complete qualifications. In *Semien*, the Seventh Circuit recognized that even under the abuse of discretion standard, some discovery may be allowed into

certain limited subjects when the plaintiff makes at least a preliminary showing that there is reason to question the fairness or impartiality of the decision. 436 F.3d at 813-14 (although discovery is normally disfavored in ERISA cases, limited discovery outside of the administrative record is appropriate to ensure that plan administrators have not acted arbitrarily and that conflicts of interest have not contributed to an unjustifiable denial of benefits). Mrs. Reimann has done so in her challenge to the credentials of the outside reviewers based on the more limited information that was initially available. When the challenge is raised, it seems only fair to allow a response, particularly in the wake of *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. __, 128 S. Ct. 2343 (2008). When there is a challenge to the objectivity and honesty of the plan administrator's decision, *Glenn* recognized, the plaintiff must have the opportunity to supplement the record (and, presumably, to conduct at least some targeted discovery). For example, a reviewing court may consider evidence about the insurance company's record of biased or unfair claims administration, or evidence about the insurance company's efforts to ensure that decision makers will be objective and independent. 128 S. Ct. at 2531; accord, *Hogan-Cross v. Metropolitan Life Ins. Co.*, 568 F. Supp. 2d 410 (S.D.N.Y. 2008) (allowing discovery related to financial conflict of interest). Evidence of both types will ordinarily not be included in the individual claim file that provides the usual administrative record in an ERISA case. This reasoning based on *Glenn* extends to Mrs. Reimann's challenge to the qualifications and expertise of the outside reviewers. If the supplement were not allowed, the appropriate remedy for review by someone not shown to have the

requisite expertise would probably be a remand for another review by someone more expert. That approach here would be pointless, especially in light of the excellent credentials of all four outside reviewers. In response to Mrs. Reimann's challenge, it seems more reasonable to allow each side to supplement that limited administrative record, as each side has done in this case. Plaintiff's objection to the record supplements with the reviewers' credentials (Dkt. No. 74) is therefore overruled.

The supplemental record shows that all of the reviewers were well qualified to evaluate Mrs. Reimann's case. The first reviewer is board certified in internal medicine, hematology, and oncology. In his career as an expert reviewer, he has conducted more than 300 reviews to determine the experimental nature of proposed treatment regimens, including autologous, allogeneic, and "mini" transplantation with high-dose chemotherapy and other cancer therapies. SAR 0113-14. The second reviewer is not merely a general surgeon. He is the chief of the division of transplantation of the department of surgery at a major university hospital, having previously served as director of kidney and pancreas transplantation of that same facility. SAR 0017. He has taught transplant surgery for many years and is board certified in general surgery, vascular surgery, and surgical critical care, and was credentialed by the United Network of Organ Sharing as a transplant surgeon for kidney and pancreas transplants. SAR 0017-18, 0020.

When Anthem submitted Mrs. Reimann's claim to IMEDECS for a third review, it requested review by a surgeon with experience and expertise with intestinal and multivisceral transplant procedures. AR 1098. The IMEDECS reviewer who reviewed Mrs. Reimann's claim is board certified in surgery, completed a residency in general surgery and a fellowship in pediatric surgery, and another fellowship in transplant surgery. The reviewer serves as assistant director of transplantation services and as an attending surgeon treating adults and children. AR 1101. Mrs. Reimann argues that the third reviewer does not have clinical experience or training in either multivisceral transplants or neuroendocrine tumors. Pl. Reply 21. However, the reviewer is a specialist in transplant surgeries, and while his experience with multivisceral transplants or neuroendocrine tumors is unknown, his report demonstrates that he thoroughly evaluated Mrs. Reimann's condition and the appropriate medical literature. The fourth reviewer is a professor and chief of hematology and oncology at a teaching hospital and has published widely in peer reviewed journals. SAR 0122-41. Anthem substantially complied with the regulations requiring it to seek advice from qualified experts.

B. *Reviewing Physicians' Failure to Contact Mrs. Reimann or Her Treating Physicians*

The physicians who reviewed Mrs. Reimann's claim did not contact her or her treating physicians to discuss her condition and to obtain a better understanding of her disease and treatment plan. See AR 0430. Mrs. Reimann

argues that this failure amounted to a procedural error under ERISA. However, nothing in the statute or regulations requires either Anthem or the independent physicians evaluating Mrs. Reimann's claim to contact her or her treating physicians. See, *e.g.*, *Trustmark Ins. Co. (Mut.) v. Schuchman*, 2004 WL 1622094, *12 (S.D. Ind. June 8, 2004) (plaintiff's position that administrator had a duty to contact plaintiff's treating physician was unsupported). The reviewers reasonably found that they had sufficient information to provide reliable judgments. The court does not find that Anthem's decision to deny Mrs. Reimann's request for coverage was arbitrary or capricious based on its failure to require the independent reviewing physicians to contact Mrs. Reimann's treating physicians.

C. *Reliance on Internal Medical Policy*

Mrs. Reimann argues next that Anthem improperly adopted internal guidelines that were more restrictive than its Health Certificate and then relied on those internal policies, rather than the language of the Health Certificate itself, to deny her claim. Anthem provided all four reviewers with a copy of an internal Anthem policy entitled "TRANS.00013 for Small Bowel and Multivisceral Transplant Including Small Bowel/Liver." Anthem told the first, third, and fourth reviewers to use their independent medical judgments. It told the second reviewer to apply the policy.

A plan administrator may not deny benefits based on an internal policy that contradicts plan terms. See, *e.g.*, *Filipowicz v. American Stores Benefit Plans Comm.*, 56 F.3d 807, 815 n.6 (7th Cir. 1995) ("interpretive guideline cannot limit coverage provided by the insurance contract"), citing *Egert v. Connecticut General Life Ins.*, 900 F.2d 1302, 1306-08 (7th Cir. 1990) (reliance on internal guidelines that were inconsistent with plan terms was arbitrary and capricious), *Baker v. Physicians Health Plan of Northern Indiana Group Health Plan*, 2007 WL 1965278, *9-10 (N.D. Ind. 2007) (defendant's reliance on plan guidelines that were inconsistent with the terms of the plan to deny coverage was arbitrary and capricious; decision was not rationally connected to the plan language or the evidence before it); *Evans v. W.E.A. Ins. Trust*, 361 N.W.2d 630, 636-38 (Wis. 1985) (reliance on internal guidelines that imposed a standard not required by the ERISA plan provisions and that were inconsistent with those provisions was arbitrary and capricious). Mrs. Reimann also cites *Reilly v. Blue Cross and Blue Shield United of Wisconsin*, 846 F.2d 416, 423 (7th Cir. 1988) (plan cannot grant complete discretion to an internal committee to determine what treatments would be considered experimental), arguing that here, as in *Reilly*, she has been arbitrarily excluded based on her status. Pl. Br. 20-24.

These cases do not apply here because there is no inconsistency or conflict between the Health Certificate and TRANS.00013, and Mrs. Reimann has not shown that the guidelines in TRANS.00013 are arbitrary. The Health Certificate defines "Covered Transplant Procedure" as any "medically necessary human organ and tissue transplant as determined by Us. . . ." AR 0094. The Health Certificate

continues by defining "medically necessary" as treatments that are determined by Anthem to be, in part, "Medically appropriate for and consistent with the . . . treatment of the Member's condition, illness, disease, or injury; . . . Provided in accordance with applicable medical and/or professional standards; . . . Known to be effective, as proven by scientific evidence, in materially improving health outcomes; . . . Not Experimental/Investigative." AR 0096. TRANS.00013 is not inconsistent with the general definitions of "Covered Transplant Procedure" and "Medically Necessary" as set forth in the Health Certificate. The document is a more specific description of Anthem's rationale in determining what sorts of multivisceral transplants are medically necessary under its policy, and what sorts of multivisceral transplants are experimental or investigative under its policy.

Because the Health Certificate does not note any "specific limitations" on transplant operations, Mrs. Reimann argues, Anthem's internal policy is more restrictive than the Health Certificate, so that its refusal to pay Mrs. Reimann's claim based on the internal policy is arbitrary and capricious. Pl. Br. 19-20, 23-24. The court disagrees. TRANS.00013 is more restrictive only in that it is more specific, addressing in detail the circumstances in which intestinal or multivisceral transplants may be appropriate and medically necessary. The specifics do not contradict any language in the Health Certificate. Nor are those specifics arbitrary. TRANS.00013 is a multi-page document that cites numerous medical publications and journals on which it is based. It is a standardized guideline based on peer-reviewed publications, government, medical society, and

other authoritative publications, and it specifically states that the Health Certificate language takes precedence over the language in TRANS.00013. AR 0152-59. Its list of contraindications, including metastatic cancer, is taken from the American Society of Transplantation in Guidelines for the Referral and Management of patients Eligible for Solid Organ Transplantation. AR 0153-54. The Health Certificate expressly allows Anthem to rely on such published professional standards in determining when a proposed treatment is experimental, investigative, or not medically necessary. AR 0060. Mrs. Reimann has not shown that TRANS.00013 imposed either inconsistent or arbitrary standards on her request for a multivisceral transplant.

Mrs. Reimann argues further that Anthem's apparent emphasis on its internal policy TRANS.00013 rather than its policy definition of "medically necessary" violated ERISA. In tune with the policies underlying 29 U.S.C. § 1133 and 29 C.F.R. § 2560.503-1(g)(1), she argues that Anthem was required to make clear the terms of her coverage so that she could make an informed decision regarding her coverage. She contends that Anthem's use of internal guidelines and its failure to inform her or her employer of those guidelines "thwarts a plan participant's ability to adequately assess the coverage they are gaining and thereby make competent decisions regarding whether to pursue alternative forms of medical insurance." Pl. Br. 21.

Again, policy TRANS.00013 is consistent with the information that Mrs. Reimann and Hillcrest were provided in the Health Certificate. It is more specific, but it is not more restrictive or arbitrary. Certainly, participants must be given sufficient information so that they can understand their coverage, and when benefits are denied, the administrator has the obligation under the regulations to explain why. See, *e.g.*, 29 C.F.R. § 2560.503-1(g)(1)(ii). However, the court is not persuaded that a plan provider must include in the plan itself all of its internal guidelines (which presumably will change as medical knowledge and practice change). The statute requires only that the administrator furnish copies of the latest updated summary plan description, annual report, terminal report, bargaining agreement, trust agreement, contract, or other establishment or operating agreements upon written request. 29 U.S.C. § 1024(b)(4). The regulations clearly contemplate that a current internal policy must be disclosed when a decision is based upon it, 29 C.F.R. § 2560.503-1(g)(1)(v)(A), which implies that it need not be disclosed earlier.

Finally, Mrs. Reimann argues that Anthem has admitted that the first two reviewers evaluated her "wholly on improper criteria." She bases the argument on Anthem's instructions to the third outside reviewer (IMEDECS), saying that the policy "has been provided solely for informational purposes. The medical policy may not be applied when formulating, or used as the basis of, the reviewer's opinion." Pl. Reply 17-18, citing AR 1098. The conclusion does not flow from the premise. As explained, Anthem did not abuse its discretion by providing

TRANS.00013 to the first or second reviewers. Its submission to IMEDECS will not be construed as an admission otherwise.

D. *"Shifting" Reasons for Denial?*

Mrs. Reimann argues that Anthem has denied her a "full and fair" review of her case by changing its reasons for its denial from "not medically necessary" to "experimental." She takes particular issue with the second review. Although the second reviewing physician concluded that the multivisceral transplant was not medically necessary, the reviewer first indicated that the treatment is not experimental (by indicating "no" to answer the question: "Based on Wellpoint medical policy, is the transplant of internal multi considered experimental/investigational?") and then that the treatment is experimental under Anthem's TRANS.00013 policy, by noting that Mrs. Reimann has metastatic carcinoid and that metastatic cancer is an absolute contraindication for a transplant procedure. Pl. Reply 9, n.3, citing AR 0258; Pl. Reply 15. In its second denial letter to Mrs. Reimann, Anthem did not report the internal inconsistency in the second reviewer's evaluation, and it maintained its prior position that the transplant was excluded because it was not medically necessary. The second letter did not use the term "experimental" at all. AR 0250. Also, Mrs. Reimann argues that Anthem abused its discretion when it submitted her claim to IMEDECS for a third review because Anthem did not request that the reviewer determine whether the treatment was medically necessary, but instead requested

that IMEDECS determine whether the procedure was experimental. Pl. Reply 7, citing AR 1114. She also argues that the evidence establishes that Anthem inconsistently interpreted the terms of the policy and that Anthem waived its ability to raise the experimental nature of the procedure as a defense to coverage in litigation. Pl. Reply 23, citing *Matuszak*, 927 F.2d at 322-323.

Mrs. Reimann is entitled to a "full and fair" review of her claim. See 29 U.S.C. § 1133(2). In determining whether there has been substantial compliance with that statutory requirement, the question is whether Mrs. Reimann was supplied with a statement of reasons that, under the circumstances, permitted a sufficiently clear understanding of Anthem's position to permit effective review. See *Dade v. Sherwin-Williams Co.*, 128 F.3d 1135, 1141 (7th Cir. 1997); *Halpin v. W.W. Grainger, Inc.*, 962 F.2d 685, 690 (7th Cir. 1992). As explained above, under the language of Mrs. Reimann's policy, "experimental" is one subset of the broader set of procedures that are not "medically necessary." Anthem's use of the term "experimental" was not a switch or change in its position. Its rationale for denying Mrs. Reimann's claim has been consistent throughout the claims process and in litigation: there is not sufficient scientific evidence to expect that the transplant surgery is likely to be beneficial for a patient as sick as Mrs. Reimann, with cancer that has metastasized beyond her liver. That lack of evidence means that the transplant fails to satisfy two closely related elements of the plan's definition of medical necessity. The transplant is both "not proven" and experimental and/or investigative. Mrs. Reimann was not

denied a full and fair review. Anthem determined, in rounds one and two, that her request for coverage for a multivisceral transplant is "not medically necessary," and then on round three found more specifically that the procedure is "experimental" for patients like her and therefore still not medically necessary.

Although the second reviewer first answered "no" to the question of whether "the transplant of internal multi" is experimental, the report as a whole shows that his second answer of "yes" was the answer he intended. The reviewer explained that he found that the procedure was experimental because, according to the Wellpoint General Transplant Selection Criteria, metastatic cancer is an absolute contraindication for transplant procedures, and "this patient has metastatic carcinoid tumor in her liver/lymph nodes." AR 0149. The substance of the report made clear that the reviewer found the procedure is not supported by scientific evidence and that he believed that in Mrs. Reimann's case the multivisceral transplant procedure would be experimental.

Anthem did not abuse its discretion in requesting, in the third review, that IMEDECS determine whether the treatment was experimental and/or investigatory and whether it was medically necessary. As used in Anthem's policy, these terms are not inconsistent. Treatments can be both "not medically necessary" and "experimental." Anthem asked IMEDECS the same basic question it had asked the two prior reviewers, but in a different way. Doing so was not an abuse of discretion.

Mrs. Reimann is correct that in some cases a change in the basis for a denial of benefits from "not medically necessary" to "experimental" can demonstrate an abuse of discretion. Pl. Br. 27, citing *Velez v. Prudential Health Care Plan*, 943 F. Supp. 332, 343 (S.D.N.Y 1996). In *Velez*, the first denial letter the plaintiff received stated that the treatment she requested was "medically unnecessary," without any explanation or specific grounds on which that determination was based. *Id*. at 336. The second denial letter stated that the treatment was "experimental" but did not explain how the policy definition had been applied. The third denial letter stated that the treatment requested was both medically unnecessary and experimental, again, without further explanation. *Id*. at 337. Unlike the plan here, the plan in *Velez* did not define "medically unnecessary" to include "experimental" treatments, and the insurer offered no explanation for its decision that Velez's treatment was excluded. Here, as previously explained, Anthem's reliance on the "not medically necessary" exclusion and its later reliance on the more specific "experimental" exclusion was not evidence of abuse of discretion. In each denial letter, Anthem explained its reasoning in ways that have been sufficiently clear and consistent throughout the process.

Mrs. Reimann also argues that because Anthem did not use the word "experimental" in denying her claim on its initial review and on her first appeal, it cannot raise the experimental nature of multivisceral transplant procedures to treat metastasized neuroendocrine tumors to defend its decision in litigation.

Relying on *Matuszak v. Torrington Co.*, 927 F.2d 320, 323 (7th Cir. 1981), and cases from other circuits, Mrs. Reimann argues that Anthem waived this basis for denying her claim. *Matuszak* stands for the proposition that the court should not defer to an administrator's explanation for its decision that was not disclosed to its plan beneficiaries until years after the fact. 927 F.2d at 322-23. However, in *Matuszak*, the administrator's explanation was not waived altogether – it was reviewed *de novo*. In another Seventh Circuit decision, the defendant was foreclosed from raising bases for denial of the plaintiff's claim in litigation that had not been raised in the claims process. See *Reich v. Ladish Co.*, 306 F.3d 519, 524 n.1 (7th Cir. 2002) (defendant may not litigate its case in "piecemeal fashion;" administrator was required to give the plaintiff every reason for its denial of benefits at the time of denial). Here, however, Anthem's specific explanation that the multivisceral transplant is experimental for patients in Mrs. Reimann's advanced condition is not inconsistent with its original, more general statement that the procedure is not "medically necessary" because it is not supported by scientific evidence. Waiver is not warranted. Anthem may rely on its determination that multivisceral transplants, for patients in Mrs. Reimann's advanced condition, are both "not medically necessary" and "experimental/investigatory" under the definition of those terms of its policy.

E. *Specifics Lacking from First Denial Letter?*

Mrs. Reimann contends that Anthem's first denial letter failed to cite to the specific provisions of the Health Certificate that Anthem relied on to deny coverage, instead stating generally that the treatment Mrs. Reimann requested is "not medically necessary." Anthem argues that it substantially complied with this regulation because it denied Mrs. Reimann's claim using and referring to the language set forth in the Healthcare Certificate ("the [multivisceral transplant] is not medically necessary, as defined in your health certificate"). See AR 0451-52. 29 C.F.R. § 2560.503-1(g)(1)(ii) requires that Anthem refer "to the specific plan provisions on which the determination [was] based." Perhaps Anthem could and should have cited the "medically necessary" definition more specifically by providing a page number or other reference point in its first letter. However, the court finds that by informing Mrs. Reimann that her claim was denied as not medically necessary, and referring her to the Healthcare Certificate, Anthem substantially complied with the requirement that it refer to the plan provision on which its determination was based. To the extent the letter failed on this score, the failure was clearly harmless. Mrs. Reimann has been fully able to pursue her rights to further review, including judicial review.

Mrs. Reimann also argues that the first denial letter failed to provide a description of any additional materials or information necessary for Mrs. Reimann to perfect her claim, as well as an explanation for why such materials or information were necessary under the regulations. Pl. Br. 6; Pl. Reply 14. Such information is required by 29 C.F.R. § 2560.503-1(g)(1)(iii). Mrs. Reimann's claim

was denied because her cancer had metastasized, a condition that Anthem recognized as an absolute contraindication to multivisceral transplants. The only information Mrs. Reimann could have provided to Anthem to perfect her claim would be (a) proof that her carcinoid tumors had not spread, or (b) evidence that the treatment was known to be beneficial for patients like her. Mrs. Reimann's condition is not in dispute. Setting forth in writing that Mrs. Reimann could perfect her claim by showing that her condition was something else would be pointless. By stating what was missing – scientific proof of health benefits – Anthem signaled with sufficient clarity what more would be needed. Anthem's failure to be more specific does not show that the denial was an abuse of discretion and was clearly harmless. Again, Mrs. Reimann was fully able to pursue her rights to appeal and judicial review.

Mrs. Reimann also contends that Anthem's first denial letter did not explain the scientific or clinical judgment for Anthem's determination, apply the terms of the plan to her medical circumstances, or provide a statement that such an explanation would be provided upon request, as required by 29 C.F.R. § 2560.503-1(g)(1)(v)(B). Pl. Br. 6, 26; Pl. Reply 14. In *Schneider v. Sentry Group Long Term Disability Plan*, 422 F.3d 621, 628 (7th Cir. 2005), the Seventh Circuit found that the notice provided to the insured that her benefits were being terminated was "indefensible as a matter of statute, regulation, and case law" because the insured was not informed what reasons motivated the outside reviewer's conclusion that she was not disabled. In contrast, Anthem's first denial

letter informed Mrs. Reimann that an outside physician reviewer had determined that "well controlled randomized studies are not available to conclude that multivisceral transplant will be 'more beneficial' than any other available standard," and had noted that the "National Comprehensive Cancer Network guidelines describe surgery options for management of metastatic carcinoid tumor, but these include wedge resection or partial hepatectomy, and they do not include multivisceral transplant." AR 0451-52. This statement, though brief, was sufficient to provide Mrs. Reimann and her doctors with a sufficiently clear understanding of Anthem's position so as to enable meaningful appeal.

The more troubling part of the letter is what Anthem's Dr. Lane said about the reviewer's qualifications. Dr. Lane told Mrs. Reimann that her claim had been reviewed by an expert with "a special interest in multivisceral transplants." AR 451. Anthem has not identified any factual basis for this claim beyond a general expectation that the outside reviewing organization would have assigned a physician with appropriate expertise to review the case. Upon reading the statement, Mrs. Reimann easily could have been misled to believe that a specialist in multivisceral transplants had reviewed her case and recommended denial. By making this exaggerated claim about "special interest," Dr. Lane and Anthem did not substantially comply with ERISA or its regulations.

What remedy is appropriate for such a violation? In ERISA cases, the court must base its remedy determination "'on what is required in each case to fully

remedy the defective procedures given the status quo prior to the denial or termination' of benefits." *Pakovich v. Broadspire Services, Inc.*, 535 F.3d 601, 607 n.3 (7th Cir. 2008), quoting *Schneider v. Sentry Group Long Term Disability Plan*, 422 F.3d 621, 629-30 (7th Cir. 2005); *Hackett v. Xerox Corp. Long Term Disability Income Plan*, 315 F.3d 771, 776 (7th Cir. 2003). Here, the first reviewer was qualified to render an opinion, but the exaggeration of his credentials might have led Mrs. Reimann to be less likely to question or appeal Anthem's denial. The exaggeration did not produce that effect, which affects the appropriate remedy. A return to the status quo, in this situation, would not require remand to Anthem for a new evaluation; the first reviewer was in fact well-qualified to evaluate Mrs. Reimann's claim. For a different claimant who could show prejudice as a result of Anthem's overstatement, a return to the status quo might require remand or referral for a new independent, binding outside review. Mrs. Reimann did not rely on Anthem's statement, and she was not deterred in pursuing her appeal rights. Anthem's and Dr. Lane's exaggeration may warrant further scrutiny in other cases, see, *e.g.*, *Glenn*, 128 S. Ct. at 2351 (noting that evidence of plan administrator's violations in other cases may be relevant in evaluating whether denial of benefits was abuse of discretion), but the court sees no further suitable remedy in this case.

F. *Omission of Judicial Review Rights*

Because Clarian appealed Anthem's decision on Mrs. Reimann's behalf, Anthem addressed its second denial letter to Clarian, stating with regard to Mrs. Reimann's appeal rights only that "all levels of Anthem's appeal process have now been exhausted." AR 0250. Mrs. Reimann argues that, with this communication, Anthem also violated ERISA by failing to inform her of her right to seek judicial review. 29 C.F.R. § 2560.503-1(g)(1)(iv) requires the plan administrator, in informing a claimant of an adverse benefit determination, to set forth "a description of the plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review." Anthem's second letter to Mrs. Reimann failed to do so.

Anthem acknowledges that its failure was an administrative error. Anthem processed the second review as a provider's appeal rather than as Mrs. Reimann's appeal. Def. Br. 6, n.4. Anthem argues that the error was harmless, however, because Anthem otherwise substantially complied with ERISA and because Mrs. Reimann voluntarily waived her internal appeal rights and proceeded directly to an external review. Def. Br. 28. This error cannot be brushed aside as lightly as Anthem would like. To comply substantially with ERISA, Anthem had to supply Mrs. Reimann with a sufficiently clear understanding of Anthem's position. As of April 14th, Anthem's position was that Mrs. Reimann had exhausted her appeal rights. Declaring this to be a mere "administrative error" and "inadvertent" does not lessen the impact that it could have on an unsuspecting claimant who might,

upon reading Anthem's letter, believe that she had no right at all to appeal Anthem's decision or to seek judicial review.

Anthem did not substantially comply with the requirement, but its failure was harmless in this case. Mrs. Reimann was fortunate enough to be represented by counsel and quickly took advantage of her right to judicial review. This lawsuit was filed on June 18, 2008, and Anthem has raised no issues as to exhaustion of administrative remedies or timeliness of any actions by plaintiff. On August 5, 2008, Mrs. Reimann agreed to waive her rights to any further internal appeal process and proceeded directly to an external review of her claim. AR 1097. In Mrs. Reimann's case, her rights to an appeal of Anthem's decision were protected in spite of Anthem's administrative error. Anthem has not raised any issue about the timing of the lawsuit with respect to the further reviews, and its decision not to do so was prudent. Although Anthem's second denial letter did not substantially comply with ERISA because if it failed to advise plaintiff of her right to seek judicial review, that failure was harmless.

G. *Prompting a Biased Evaluation?*

When Anthem submitted its review request to IMEDECS (and later to NMR), it stated in its cover letter that it had already deemed the treatment to be experimental and not medically necessary. Mrs. Reimann argues that this was a misrepresentation and prompted a biased evaluation. Pl. Reply 19. The

regulations require that the decision under review not be given deference. See 29 C.F.R. § 2560.503-1(h)(3)(ii) (to ensure full and fair review, claims procedures must "provide for a review that does not afford deference to the initial adverse benefit determination and that is conducted by an appropriate named fiduciary of the plan"). The regulations do not require that subsequent reviewers be kept in the dark regarding the results of prior evaluations, only that on review the results not be given deference. It is reasonable to give a reviewer notice of the reasons for the earlier decision, just as it is reasonable for a court of appeals to know the trial court's reasons for a decision even where the review is *de novo*. There is no indication that the IMEDECS reviewer gave any deference to the previous evaluations. The court finds no error by Anthem in this regard.

H. *IMEDECS' State Certification*

The status of IMEDECS' Indiana certification to perform independent medical reviews when it reviewed Mrs. Reimann's case is the subject of dispute. Mrs. Reimann contends that its certification had lapsed with the Indiana Department of Insurance, and she accuses Anthem of failing to ensure that its chosen reviewing organization was appropriately certified and in compliance with state requirements. Pl. Reply 19. She argues that because IMEDECS was not officially certified when Mrs. Reimann's claim was reviewed, Anthem could not use IMEDECS' review to deny Mrs. Reimann's claim. Pl. Reply 20.

Indiana Code § 27-8-29-19 requires that independent review organizations such as IMEDECS be certified annually. To be certified, Indiana Code § 27-8-29-19(c)(3) requires the independent review organization to file certain information relating to its determinations with the department of insurance on or before March 1 every year. If an organization fails to comply with this requirement, the department of insurance "may suspend or revoke an independent review organization's certification if the department finds that the independent review organization is not in substantial compliance with the certification requirements under this action." Ind. Code § 27-8-29-19(e). In 2008, IMEDECS failed to submit a renewal application for certification and did not submit the requisite information regarding its claims determinations. Danielle Fuller Aff. ¶¶ 6, 8.

Anthem has shown that although IMEDECS' Indiana certification would have expired on December 31, 2005, the department of insurance informed IMEDECS on December 21, 2005 that its deadline for recertification was extended pending the department's development of the recertification process. Deahna Montaque Aff. ¶ 8, Ex. A. Once that process was complete, the department said, it would notify IMEDECS of the completion and allow it 30 days to produce any documentation needed for the recertification process. Until that redevelopment was complete, IMEDECS was told, its certification would remain valid. The department of insurance did not contact IMEDECS again until July 2008, informing it that its certification had expired on December 31, 2007 but could be

renewed for 2008 if IMEDECS submitted certain information before August 15, 2008. *Id*., ¶ 10, Ex. B. IMEDECS submitted the requested information on August 14, 2008, and responded on August 29, 2008 when the department of insurance requested additional information. *Id*., ¶¶ 12-13, Exs. C, D.

Anthem argues that, based on these exchanges, the department of insurance should be estopped from taking the position that IMEDECS was not certified as an independent review organization with the State of Indiana, and that even if the department of insurance is not estopped, IMEDECS was in substantial compliance with the statutory requirements for certification. Def. Surreply 7-9. In any event, Anthem contends, the argument is moot because Anthem submitted Mrs. Reimann's case to a second independent review organization, National Medical Reviews, Inc. (NMR), on September 3, 2008. SAR 0002-03. Anthem's submission to NMR duplicated the submission to IMEDECS, and like IMEDECS, NMR's review upheld Anthem's denial determination.

There is no dispute about any of these facts. Based on the department's letter of December 21, 2005, the IMEDECS certification for Indiana remained valid throughout the time that IMEDECS reviewed Mrs. Reimann's case. Anthem was entitled to consult IMEDECS and to rely on its work. Even if there were a genuine problem here, and there was not, Anthem found a reasonable remedy by submitting Mrs. Reimann's claim for a fourth review by NMR. If the court had found that the IMEDECS review was improper, the obvious remedy would have

been to remand to Anthem for submission to a properly certified independent review organization on an expedited basis. Anthem already did so of its own accord. Mrs. Reimann has not challenged NMR's certified status. Her challenge to IMEDECS' status is not persuasive.

I. *Objections to the Fourth Review*

Mrs. Reimann argues that Anthem, by submitting her claim for a fourth outside review on its own initiative and without advance notice to her, disregarded the letter and spirit of ERISA. Dkt. 52 at 2, citing *Halpin*, 962 F.2d 685 (7th Cir. 1992); *Reich*, 306 F.3d at 524 n.1 (ERISA plan "was required to give [the plaintiff] every reason for its denial of benefits at the time of denial. . . . . It may not add new reasons as litigation proceeds"). For the reasons set forth above, the court disagrees with Mrs. Reimann's assessment. NMR was a completely new reviewer. It generated a completely different report, as expected from a new external and independent review. Anthem wrote a fourth denial letter based on that report, as it was required to do if it intended to rely on the NMR review to uphold its previous determination that the multivisceral transplant was not covered under Mrs. Reimann's plan. Finally, Anthem did not switch its reasons for denying Mrs. Reimann's claim. In its fourth denial letter, Anthem incorporated NMR's review by reference. SAR 0004-05. Consistent with the three prior reviews, NMR determined that the multivisceral transplant in Mrs. Reimann's case would be experimental and/or investigative and not medically necessary within the meaning of the plan. SAR 0014-15.

Mrs. Reimann also argues that Anthem's submission of her claim for a fourth review is an admission that the prior reviews were worthless. Dkt. 52 at 3-4. As above, the court disagrees. The parties are engaged in litigation. Because

Mrs. Reimann challenged the IMEDECS certification, Anthem took the initiative to submit Mrs. Reimann's case for a fourth independent review and agreed to be bound by an outside finding that the proposed transplant surgery would be medically necessary. If anything, the court should encourage plan administrators faced with a procedurally questionable review to seek out an independent review that will fulfill the purposes and spirit of ERISA and its regulations, not punish them by setting evidentiary traps. Anthem's submission of the fourth review cannot fairly be treated as an admission that any of the prior reviews were inadequate or unreasonable.

To sum up the procedural points, the court rejects most of plaintiff's challenges. Where Anthem did make procedural errors, those errors did not cause harm to Mrs. Reimann or undermine the fairness and thoroughness of the review of her case. The procedural errors do not call for a remedy that would require Anthem to cover the costs of the proposed transplant surgery.

III. *Whether the Denial Was an Abuse of Discretion*

The key substantive question before the court is whether Anthem's denial of coverage for the proposed multivisceral transplant to treat metastasized cancer was an abuse of discretion. See *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. —, —, 128 S. Ct. 2343, 2348 (2008). The Supreme Court has cautioned against formulas that will take the place of actual judging or that serve as "instruments

of futile casuistry." *Glenn*, 128 S. Ct. at 2352. At the same time, cases identifying relevant factors can provide a useful way to organize thoughts. The Seventh Circuit has identified as relevant factors the impartiality of the decision maker, the complexity of the issue, the process afforded to the parties, the extent to which the decision maker used help from outside experts where necessary, and the soundness of the fiduciary's reasoning. *Chalmers v. Quaker Oats Co.*, 61 F.3d 1340, 1344 (7th Cir. 1995); *Hughes v. Life Ins. Co. of North America*, 112 F. Supp. 2d 780, 793 (S.D. Ind. 2000).

A. *Impartiality*

Plaintiff emphasizes Anthem's financial stake in the decision here. Anthem administers the plan that includes Mrs. Reimann. Anthem also underwrites that plan, meaning that it takes on the financial risk that claims and expenses may exceed premiums. In other words, the one million dollars it would take to provide this multivisceral transplant for Mrs. Reimann would come directly from Anthem's bottom line. This situation produces the type of conflict of interest addressed in *Glenn*. The conflict is a factor the court should consider in determining whether the fiduciary abused its discretion. 128 S. Ct. at 2350-51.

Glenn recognized that such a conflict could be especially important if the circumstances suggest a high likelihood that the financial interest affected the decision to deny benefits, such as where an insurance company has a history of

biased claims administration. *Id*. at 2351. *Glenn* also recognized that such a conflict could prove "less important (perhaps to the vanishing point) where the administrator has taken active steps to reduce potential bias and to promote accuracy. . . ." *Id*.

The administrative record here shows an unusually thorough effort to ensure the independence and impartiality of the decision-making. Anthem did not make the medical decision internally at all. It referred the case four times to expert and independent outside reviewers. Anthem itself did not even choose the outside reviewers. It referred the case to companies that act as clearing-houses for such outside and independent reviews of difficult medical cases. Those clearing-houses selected the individual reviewers and required the reviewers to certify their financial and professional independence relative to the case and the interested parties. Perhaps most telling here, Anthem's third and fourth reviews were under a procedure in which Anthem agreed to be bound by the decisions of the outside reviewers. If either had concluded that the proposed transplant was medically necessary, Anthem would have been required to cover the costs.

Plaintiff argues that the use of Anthem's internal policy on transplants (with the "absolute contraindication" of metastasized cancer) shows that the reviews were not truly impartial. The second reviewer was told to apply that policy. The other three were given the policy for informational purposes but were asked to exercise their independent judgment. Recognizing the theoretical potential for

abuse of such internal policies, the court finds the plaintiff's argument is not persuasive here. The key provision of the challenged policy – the list of contraindications – was taken directly from an expert and impartial source, the American Society of Transplantation's guidelines for solid organ transplants.

ERISA regulations recognize that an insurer may properly rely on such policies. See 29 C.F.R. § 2560.503-1(g)(1)(v)(A) (where denial is based on internal rule, guideline or policy, denial letter must either provide a copy or state that copy is available free of charge). The use of such policies, especially where they are based on neutral expert judgments, can promote fair and consistent decision-making and can avoid the need for case-by-case battles of experts. See *Bechtold v. Physicians Health Plan of Northern Indiana*, 19 F.3d 322, 326 (7th Cir. 1994) (affirming denial of coverage for autologous bone marrow transplantation as treatment for solid tumors, including breast cancer).

The court is aware of the possibility that the outside review process, despite all these appearances of objectivity and independence, could nevertheless be biased in favor of the insurance company in various subtle ways. That possibility has not been realized in this case. Perhaps the best evidence is the combination of (a) the consistency of the analysis and conclusions from the four different reviewers and (b) the absence of evidence showing that a multivisceral transplant is a proven and accepted treatment for patients like Mrs. Reimann with metastasized cancer beyond the liver. In other words, the review here was

impartial and, despite the high financial stakes, Anthem took steps that took the conflict of interest to the "vanishing point" described in *Glenn*.

B. *Complexity of Issues*

This factor weighs against a finding of an abuse of discretion here. The medical literature in the record shows that multivisceral transplants remain a rare and high-risk form of treatment for a wide range of grave diseases. The surgery poses a daunting set of challenges to surgeons and their patients even for those diseases where the procedure has gained some acceptance. The issues here are even more complex, where some of the world's leading experts propose to try the surgery under circumstances where it has been tried rarely if ever. Where the talented doctors who have looked at Mrs. Reimann's case – both the treating doctors and the outside reviewers – have reached opposite conclusions about the state of the scientific evidence, it is difficult for a court to find an abuse of discretion.

C. *Process Afforded to the Parties*

In general, the process afforded to Mrs. Reimann and her doctors has been fair, thorough, and prompt. Four independent outside reviewers considered the relevant information, including the information that plaintiff's lawyers assembled from her doctors and medical records. Anthem even went so far as to delegate the decision completely in the case of the third and fourth reviews. As discussed

above, there were some problems in the procedures Anthem used, including the troubling exaggeration of information about the first reviewer's qualifications. The court is satisfied, however, that none of those procedural problems affected the final decision or the quality of the reasoning. The court must conclude that Mrs. Reimann's doctors have known from the beginning the type of information that would be persuasive in a case like this. They have been unable to provide it – not for lack of trying, but because it does not exist.

D. *Use of Outside Experts*

As noted, Anthem made extensive use of independent outside experts, as appropriate for this difficult case. This factor also weighs against a finding that Anthem abused its discretion.

E. *Soundness of the Fiduciary's Reasoning*

The reasoning here was clear and sound. Anthem adopted the reasoning of the outside experts. They reasonably concluded that a multivisceral transplant simply has not been shown to be beneficial to patients who are as sick as Mrs. Reimann is, with cancer that has metastasized beyond the liver. Under the terms of the policy, the proposed surgery is excluded because it is experimental and/or investigatory, and is not medically necessary.

Nothing in this opinion should be understood as critical of Mrs. Reimann, the doctors who are treating her at Indiana University Hospital, or their recommendation for the transplant surgery. The court recognizes that Dr. Vianna and Dr. Lillemoe have great expertise in their fields. Both are capable of providing superb state-of-the-art care for gravely ill patients. Perhaps more to the point, both doctors are capable of *extending* the state of the art to improve available and accepted care. Both have offered reasoned explanations for their opinions that the proposed multivisceral transplant surgery might benefit Mrs. Reimann and might be the best or only hope for curing her.

The question before the court, however, is whether Anthem abused its discretion in finding the proposed surgery is unproven as a therapy for patients like Mrs. Reimann. On this record, the answer is clearly no. All four independent experts came to that same conclusion, which is consistent with all the evidence, including the medical literature and the standards set by independent expert groups of physicians. Dr. Vianna and Dr. Lillemoe and Dr. Tzakis did not dispute that conclusion with evidence. Dr. Vianna wrote that multivisceral transplants "have been clinically effective since 2001" and that Indiana University Hospital has an 89 percent survival rate for patients who have them. AR 0475. Dr. Vianna, Dr. Lillemoe, and Dr. Tzakis all testified that multivisceral transplants "are known to be effective in materially improving the health outcome of patients suffering from carcinoid tumors such as Mrs. Reimann." AR 0476, 0504, 0644. They did *not* say that multivisceral transplants are known to be effective in

treating patients with metastatic cancer, especially where the metastases extend beyond the liver. The metastasis was the factor that persuaded the outside reviewers that the surgery is not proven under these circumstances.

Also, nothing in this opinion should be understood as expecting Mrs. Reimann or her doctors to come forward with evidence that she would certainly benefit from the proposed transplant surgery. Such certainty is not available even for treatments that are widely accepted as appropriate and proven. Under the terms of the plan, what would be needed here is a more modest showing: scientific evidence that the proposed transplant surgery is "known to be effective . . . in materially improving health outcomes," AR 0096, that the treatment "improves net health outcomes of the total population for whom the service might be proposed by producing beneficial effects that outweigh any harmful effects," that the treatment would be "as beneficial for the total population for whom the service might be proposed as any established alternatives," or that the treatment would "improve the net health outcomes of the total population for whom the service might be proposed under the usual conditions of medical practice outside clinical investigatory settings." AR 0060. Such evidence has not been produced here.

There is a temptation here to argue that, because all other forms of treatment have not been successful with Mrs. Reimann, it must be "medically necessary" to keep trying even unproven therapies such as a multivisceral

transplant. The argument takes on extra force when doctors as eminent as Dr. Lillemoe, Dr. Vianna, and Dr. Tzakis recommend this treatment. The argument has considerable emotional force, especially where the patient suffers from a progressive disease that will cause death if not treated successfully, and no other form of therapy offers hope.

The legal response to this appealing argument is that Anthem simply did not agree to cover the costs of any form of therapy that such a patient's doctors – even extraordinarily talented doctors – might deem worth trying when they have run out of proven alternatives. Medical knowledge and skill are advancing continually. Talented and dedicated doctors like Dr. Vianna and the others who are treating Mrs. Reimann are looking constantly for ways to improve their treatment of gravely ill patients. Anthem and other insurers recognize that they cannot keep insurance premiums from rising even faster than they already are without some meaningful limits on the expenses they can be expected to cover. The standard of medical necessity applied here is not novel or selfish. It is an established mechanism for keeping medical costs under at least minimal control for all who pay for health insurance. It has been considered and applied in this case carefully and fairly. The court cannot find an abuse of discretion in Anthem's denial of coverage for this unproven proposed treatment.

Conclusion

For the foregoing reasons, the court will enter judgment in favor of defendant Anthem.

So ordered.

Date: October 31, 2008

DAVID F. HAMILTON, CHIEF JUDGE
United States District Court
Southern District of Indiana

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